

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<b>In re Application of:</b>	<b>Michael Austin, Don Robinson, Dennis R. Boulais, Praveen Kulkarni, Toby Freyman, Samuel J. Epstein, Wendy Naimark, Marlene Schwarz</b>
<b>Application No.:</b>	<b>10/797704</b>
<b>Filed:</b>	<b>March 9, 2004</b>
<b>For:</b>	<b>Coated Medical Device and Method for Manufacturing the Same</b>
<b>Examiner:</b>	<b>Laura Estelle Edwards</b>
<b>Group Art Unit:</b>	<b>3738</b>

Docket No.: S63.2B-14067-US01

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

This is in response to the Advisory Action dated February 19, 2010 and the Final Office Action dated **November 30, 2009**, which rejected claims 17, 19-29 and 36-39 under 35 USC § 103 over a primary combination of over Pacetti (US 2005/0074544) in view of Shibata (JP 11-111423). Some of the rejections included citation to additional references; however, this response addresses the primary combination of Pacetti and Shibata.

The rejections asserted in the Office Action are traversed because 1) the record is incomplete and does not support the rejections; and 2) a person of ordinary skill in the art would not have considered the claimed subject matter obvious in view of Pacetti and Shibata.

Incomplete Record

The record is incomplete because a translation of Shibata has not been provided. Shibata is a Japanese reference that does not appear to have a direct US or other English language equivalent. An English abstract of Shibata was provided by the Examiner, but not a translation of the underlying reference. Applicants requested a translation in the response filed August 12, 2009. The subsequent Final Office Action, mailed November 30, 2009, acknowledged Applicants' request and indicated that a translation should be available within two months.

On March 1, 2010, the effective 3-month deadline to respond to the Final Office Action, the Examiner sent a facsimile to Applicants with a copy of US 6111345 and a statement that the reference is an English Language Equivalent of Shibata (JP 11-111423). This assertion is

traversed.

Applicants assert that US 6111345 cannot be considered a translation of Shibata because it does not mention the application number (JP10030049) of the Shibata reference, or the publication number (JP 11-111423). US 6111345 lists seven Japanese patent applications that are related by priority – see column 1, lines 9-16; however, none of the listed application numbers correspond to the Shibata reference being applied in the rejection. There is nothing that indicates that US 6111345 is a translation of Japanese application JP10030049, or a translation of publication JP 11-111423.

US 6111345 claims priority to several Japanese applications and therefore includes subject matter that goes beyond the disclosure of the Shibata reference. Therefore, US 6111345 is not useful to evaluate the actual teachings of the applied Shibata reference. The Examiner's submission of US 6111345 does not amount to provision of the requested translation of Shibata, and the record remains incomplete.

On the basis of the current record, the Shibata reference itself cannot be relied upon – only teachings from the English Abstract that was provided by the Examiner. See MPEP § 706.02(II).

The rejections rely upon teachings from Shibata that go beyond the scope of the English Abstract. See e.g. Office Action at page 2, discussing “blades (500/100) for removal of excess coating material.” The English abstract does not mention “blades” or reference characters 500 or 100. Therefore, the current rejections rely upon teachings that are not in the current record, and the applied references do not disclose or suggest a “doctor blade in proximity to the first roller surface positioned to remove excess coating material from the first roller surface” as recited in independent claim 22.

An obviousness rejection requires a suggestion of all limitations in a claim. See *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003).

Based upon the current record and lack of an English translation of the actual Shibata reference, Applicants request withdrawal of the rejections asserted in the Final Office Action.

Non-Analogous Art

The Shibata reference is non-analogous prior art. The pending claims are directed to “A system for coating a stent....” See e.g. independent claim 22. A person of ordinary skill in the art, after reviewing Applicants’ disclosure, would recognize that a stent is an intraluminal medical device intended for use within a human body. As such, the stent and any coatings must be biocompatible.

The title of Shibata is “Method of Forming Film of Spark Plug.” See English Abstract. The problem to be solved by Shibata is “To provide a spark plug which can inhibit generation of a spike noise in a detected waveform of an ion current detecting device.” See English Abstract.

A person of ordinary skill in the art of coating stents would not have looked to the spark plug art for guidance. A spark plug cannot be considered equivalent to a stent, and a person of skill in the art would not have had any reason to look to the field of the Shibata reference in seeking guidance in coating biocompatible medical devices. Therefore, Applicants assert that Shibata is non-analogous art that is not available against the pending claims.

Combination

A person of ordinary skill in the art would not have been motivated to modify Pacetti in view of Shibata because there is no need - the Examiner’s proposal to modify Pacetti stems from an impermissible hindsight attempt to reach the rejected claims.

The rejection asserts, “it would have been obvious...to utilize an indirect coating arrangement as taught by Shibata in place of the Pacetti direct coating arrangement as an alternative arrangement for coating the stent to allow for a more metered supply of coating material.” See Office Action mailed May 12, 2009 at page 3.

Thus, the rejection characterizes the single roller system of Pacetti as a “direct coating arrangement” and the multiple roller system of Shibata as an “indirect coating arrangement.” While the broad generalizations can be considered accurate, the rejections use these generalizations to draw generalized conclusions that are not supported by the teachings of Pacetti and Shibata.

For example, the rejection states that using an indirect coating arrangement would

enhance uniformity of the coating when compared to a direct coating arrangement. See Office Action mailed May 12, 2009 at page 3. The rejection does not compare the actual Pacetti device to the Shibata device, but instead attempts to compare broadly generalized direct and indirect coating systems. The Final Office Action included further assertions as to why the Examiner expects an indirect coating arrangement to be better than a direct arrangement (See e.g. page 5).

The assertions contained in the rejection are merely speculative, and amount to conclusory statements that are not supported by the record. The Examiner's assertions effectively conclude that the Shibata spark plug coating system is capable of providing a more uniform coating than the Pacetti system. There is no basis for such a conclusion. The Examiner has not cited to any prior art teaching that an indirect coating arrangement generally provides better results than a direct coating arrangement. Absent such a broad generalized teaching, there would be no reason to modify Pacetti to change the device generally from a direct coating system to an indirect coating system.

It is possible that the Pacetti system, after being modified to use the rollers from Shibata, would produce coatings that were less uniform or otherwise less desirable than the original Pacetti system. From the actual teachings of Pacetti and Shibata, it is unclear how a modified Pacetti device would function compared to the original Pacetti device.

The rejection ignores specifics of the Shibata device that would undermine the generalized conclusions asserted in the rejection. For example, although the rejection characterizes Shibata broadly as teaching an "indirect" two roller system, Shibata actually discloses a specialized intaglio two roller system configured to provide the coating material in particular shapes, such as bands or letters. With reference to US 6111345, asserted by the Examiner to be a translation of Shibata<sup>1</sup>, the "indirect" coating system includes a marking roller 2200 and a transfer roller 2300. The marking roller 2200 includes recesses 2201a that define the shapes/letters of the final desired coating. Coating material oriented in the recesses 2201a of the marking roller 2200 is transferred to the transfer roller 2300 and subsequently applied to the spark plug. See e.g. Figs 27A and 28, provided below, and column 20, line 31-column 21, line 40.

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<sup>1</sup> Applicants' discussion of US 6111345 does not amount to a concession that the US reference represents an accurate translation of the applied Japanese Shibata reference.

FIG. 27A

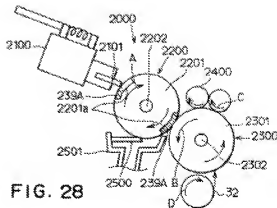


FIG. 28

The teachings of Shibata do not support the broad generalized statements that an indirect roller coating arrangement would be better or would provide more uniform coatings than a direct roller coating arrangement.

A person of ordinary skill in the art, when viewing each of the Pacetti and Shibata references as a whole without the benefit of impermissible hindsight, would not have been motivated to modify Pacetti as proposed in the rejection. A *prima facie* case of obviousness has not been presented against the pending claims, and Applicants request withdrawal of the rejections that apply a combination of Pacetti in view of Shibata.

Respectfully submitted,  
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Date: March 1, 2010

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